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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/788,847

02/27/2004

Yusuke Nakamura

25371-021 CIP

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EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

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DELIVERY MODE

10/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/788,847	<b>Applicant(s)</b> NAKAMURA ET AL.	
	<b>Examiner</b> Michael D. Burkhart	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 and 02 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt and entry of the amendment dated 8/2/2007 is acknowledged. After entry of the amendment, claims 15 and 62 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Drawings***

The drawings were received on 8/2/2007. These drawings are acceptable.

#### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) and 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of prior-filed applications, Application Nos. 60/324,261, 60/391,666 and PCT/JP02/09876, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the above

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documents discloses the use of small interfering RNAs (siRNA) in the claimed method, i.e. as recited in claim 62. For PCT/JP02/09876, a review of the international application (WO 03/027143) does not reveal the use of siRNA. The above documents disclose using antisense RNAs, which are different from siRNAs in sequence and structure (i.e. siRNAs are double-stranded versus single-stranded antisense RNAs). The first disclosure of the use of siRNA is found in provisional application, 60/450,644. Hence, claim 62 and embodiments of claim 15 that encompass the use of siRNA, are given a priority date of 2/28/2003, the filing date of the 60/450,644 application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is also noted that the foreign priority document, CA 2,399,569, does not disclose the use of siRNA.

***Claim Rejections - 35 USC § 112***

Claims 15 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using the ZNFN3A1 protein set forth in SEQ ID NO:2 and encoded by a portion of SEQ ID NO: 1, does not reasonably provide enablement for other ZNFN3A1 proteins comprising two or more substitutions, partial peptides of SEQ ID NO: 2, or ZNFN3A1 proteins encoded by DNA that hybridizes to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This**

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**rejection is maintained for reasons made of record in the Office Action dated 5/2/2007, and for reasons set forth below. Claim 62 has been added due to amendment of the claims.**

***Response to Arguments***

Applicant's arguments filed 8/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that claim 15 has been amended to require SEQ ID NO: 2. Such is not convincing because the claim still recites fragments of SEQ ID NO: 2 (see line 5), which falls under the category of "partial peptides" found above, and does not require the entirety of SEQ ID NO; 2.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for RNAi that inhibit the activity of the protein of SEQ ID NO: 2, does not reasonably provide enablement for methods of screening for any other compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This rejection is maintained for reasons made of record in the Office Action dated 5/2/2007, and for reasons set forth below.**

***Response to Arguments***

Applicant's arguments filed 8/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that inhibition of cell proliferation could be specifically linked to ZNFN3A1 by the use of negative controls, i.e. cells that do not express ZNFN3A1.

Such is not convincing for the reasons set forth in the previous Office Action, i.e. there is still no link between inhibition of proliferation and inhibition of ZNFN3A1. The negative

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controls above would be, absent evidence to the contrary, sensitive to the broad-spectrum anti-proliferative compounds, such as doxorubicin or anthracycline, set forth in the previous Office Action. If the skilled artisan were to practice the method as claimed with such agents, and include the negative control cells, the claim language still requires these compounds be labeled as inhibitors of ZNFN3A1 because they inhibit proliferation. Furthermore, it is noted that the features upon which applicant relies (i.e., the use of negative control cells not expressing ZNFN3A1) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Finally, applicants fail to point out where in the specification support may be found for the method step of using negative control cells that do not express ZNFN3A1.

Claims 15 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is maintained for reasons made of record in the Office Action dated 5/2/2007, and for reasons set forth below. Claim 62 has been added due to amendment of the claims.**

***Response to Arguments***

Applicant's arguments filed 8/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that the phrase "the proliferation" has been amended to recite "proliferation." However, a reading of the claim reveals no such amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Shiff et al (J. Clin. Invest., 1995). **This is a new rejection necessitated by amendment of the claims.**

Specifically, the claim limitations found in canceled claim 5 (and claim 1) have not been incorporated into claim 15. The claims no longer require that SEQ ID NO: 2 promote cell proliferation or activate transcription of a target gene, as recited in canceled claim 5. Thus, the scope of the claims has been broadened to include using any cell that inherently expresses SEQ ID NO: 2, regardless if the above functions of SEQ ID NO: 2 were recognized or not.

HT-29 colon cancer cells inherently express SEQ ID NO: 2, ZNFN3A1, according to the instant specification, see e.g. the immunoblot in Fig. 14 and page 10, lines 4-5. Shiff et al teach the culture of HT-29 colon cancer cells in the presence of the compounds sulindac and sulindac sulfide, and the effects of each compound on HT-29 proliferation were evaluated, including proliferation in the absence of the compounds. Both compounds inhibited proliferation of the HT-29 cells, and thus would be selected as inhibitors of ZNFN3A1, according to the instant claim language. See page 493, second column, third full ¶ to page 494, and Figures 1-2.

Claims 15 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Costa et al (US 20030157531 A1, published 8/21/2003, effective filing date 12/13/2001). **This is a new rejection necessitated by amendment of the claims, as set forth above, and given that claim 62 is a new claim.**

HCT116 cancer cells inherently express SEQ ID NO: 2, ZNFN3A1, according to the instant specification, see e.g. the immunoblot in Fig. 14 and page 10, lines 4-5. Costa et al teach the culture of HCT116 colon cancer cells in the presence of siRNA compounds, and the effects of the compounds on HCT116 proliferation were evaluated, including proliferation in the absence of the compounds (e.g. mock transfection, or treatment with other siRNA with different specificities). siRNA compounds were identified that inhibited proliferation of the HCT116 cells up to 50% compared to control cells, and thus would be selected as inhibitors of ZNFN3A1, according to the instant claim language. See page 17, ¶s [0157] - [0158].

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhardt whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhardt  
Examiner  
Art Unit 1633

/Joseph Woitach/  
Joseph Woitach  
SPE 1633